SPECIAL 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Line Extension to the TRIO® Spinal System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person:	Simona Voic Regulatory Affairs Project Manager Stryker Spine 2 Pearl Court, Allendale, NJ 07401 Tel: (201) 760 - 8145
Date of Summary Preparation:	September 8, 2006

Device Identification

Proprietary Name:	TRIO® + Spinal System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Pedicle Screw Spinal System 21 CFR §888.3070
Device Product Code:	87 MNH: Spondylolisthesis Spinal Fixation System 87 MNI: Orthosis, Spinal, Pedicle Fixation

Predicate Device Information:

K032855 – Stryker Spine MAPS System (renamed Stryker Spine Trio® System)
K052971 – Stryker Spine TRIO® Spinal System
K013823, K043473 – Stryker Spine Xia® Spinal System
K012870 – Stryker Spine Xia® Stainless Steel System
K050461 – Stryker Spine Xia® 4.5 Spinal System
K951725 – Stryker Spine Osteonics Spinal System

Predicate Device Identification

The Stryker Spine TRIO® Spinal System is a thoraco-lumbar posterior fixation system comprised of bone screws, rods, and connectors. The components are available in a variety of lengths in order to accommodate patient anatomy and are fabricated from titanium alloy.

Description of Device Modification

This submission is intended to introduce TRIO®+ Spinal System, as a line extension to TRIO® Spinal System. The subject system consists of Titanium alloy bone screws, rods, and connectors, offered in a variety of lengths.

Intended Use:

The TRIO® and TRIO®+ Spinal Systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocations, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The TRIO® and TRIO®+ Spinal Systems are also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the development of a solid fusion mass.

The TRIO® and TRIO®+ Spinal Systems are sacral/iliac screw fixation systems indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, kyphosis and/or lordosis), tumor, pseudoarthrosis and review of failed fusion attempts.

The TRIO® Spinal System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, and the Multi-Axis Cross Connectors.

The TRIO®+ Spinal System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, Xia® Pre-bent Rods, and the Multi-Axis Cross Connectors.

Statement of Technological Comparison:

The subject components share the same intended use, material, and basic design concepts as that of the predicate device: TRIO® Spinal System [K032855 (formerly MAPS System) and K052971]. Mechanical testing also demonstrated comparable mechanical properties to the predicate devices including the Xia® Spinal System (K013823 &K043473), Xia® Stainless Steel Spinal System (K012870), Xia® 4.5 Spinal System (K050461) and the Osteonics Spinal System (K951725).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1 2006

Stryker Spine
% Ms. Simona Voic
2 Pearl Court
Allendale, New Jersey 07401

Re: K062698
Trade/Device Name: Stryker Spine TRIO® and TRIO® + Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, and MNH
Dated: September 7, 2006
Received: September 11, 2006

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

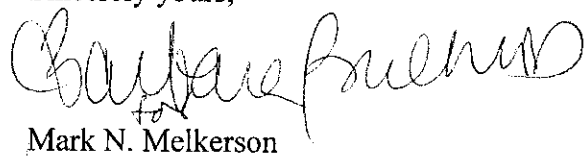
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, and Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062698 854/1

Indications for Use

510(k) Number (if known): _____

Device Name: Stryker Spine TRIO® and TRIO®+ Spinal Systems

Indications for Use:

The TRIO® and TRIO®+ Spinal Systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocations, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062698